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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,229	03/18/2005	Daisuke Itoh	2005_0470A	6230

513 7590 04/05/2011

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ART UNIT	PAPER NUMBER
1782	

NOTIFICATION DATE	DELIVERY MODE
04/05/2011	ELECTRONIC

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/528,229
Filing Date: March 18, 2005
Appellant(s): ITOH ET AL.

Amy E. Schmid
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 01/13/2011 appealing from the Office action mailed 05/17/2010.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1-7 and 10-12 are pending and rejected in the application.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

EP 0925915	Shiiki et al.	06-1999
6.159.416	Kawakami et al.	12-2000

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

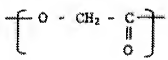
Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-7 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shiiki et al. (EP0925915, hereinafter "Shiiki") in view of Kawakami et al. (US 6,159,416, hereinafter "Kawakami").

In regards to claims 1-7, Shiiki discloses a gas barrier multi-layer hollow container with a polyglycolic acid layer [0028]. The aliphatic polyester layer is comprised of a glycolic acid homopolymer [0065 and table 1]. The polyglycolic acid useful is a polymer containing a repeating unit represented by the following formula (1):



(1)

This is the formula of the instant applicant's recurring unit of the glycolic acid polymer (pg. 7 lines 19-23). Shiiki discloses that the crystalline aliphatic polyester is glycolic acid

homopolymer [0031]. The blow molding process to make the hollow container includes a stretch blow molding process [0052]. Thus, the container has a layer that is a stretched product of crystalline aliphatic polyester.

In regards to claim 10, Shiiki discloses that the multi-layer hollow container has a layer of polyglycolic acid [0013], thus the polyglycolic acid is in the form of a film.

In regards to claim 11, Shiiki discloses that the polyglycolic acid is a layer of a hollow container [0013], thus in the form a bottle.

In regards to claim 12, Shiiki discloses that various thermoplastic resin layers (polymer layer) may be laminated to the polyglycolic acid layer [0019-0020].

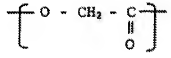
Shiiki does not disclose that the aliphatic polyester has a crystal melting point higher by at least 3°C and 5°C than that of an un-stretched product, the sub-dispersion peak temperature, the main dispersion peak temperature and the orientation degree measured by wide-angle X-ray diffractometry.

Shiiki discloses that when the Tm of the polyglycolic acid is lowered, the processing temperature of the polymer can be lowered, therefore thermal decomposition upon melt processing can be reduced [0031]. The crystallization rate of the polyglycolic acid can also be controlled by copolymerization to improve its extrudability and stretchability [0031]. Shiiki discloses that the "stretch blow molding process" is a process in which stretching is conducted upon blow molding, thereby orienting the molecular chain of a polymer to enhance the physical properties of the polymer such as transparency, strength, elastic modulus and gas barrier properties [0052]. In order to enhance such physical properties, it is essential to keep a parison at

a temperature not higher than its melting point, but not lower that its glass transition point upon stretch blow molding [0052].

Shiiki is silent with regards to the stretched product being obtained by stretching the glycolic acid homopolymer at 45-60°C at a stretching ratio exceeding 3x3 times.

Kawakami discloses a polyglycolic acid film formed from a thermoplastic resin material which comprises polyglycolic acid having a repeating unit represented by the following formula (1):



(1)

(abstract).

The polyglycolic acid film can be formed into a stretch blow molded container (col. 12 lines 29-33). The temperature conditions for the stretch blow molding are Tg 70°C or lower (col. 12 lines 64-65). The resin temperature upon stretch blow molding is controlled to 30-100°C (col. 13 lines 26-28). The preform is stretched at a draw ratio higher than one time but not higher than 10 times in a machine direction (col. 13 liens 29-30). The blow up ratio is generally 1.5-10 (col. 13 lines 37-38).

It would be obvious to one of ordinary skill at the time of the invention to substitute the stretch blow molding conditions of Kawakami for the stretch blow molding conditions of Shiiki, because the films of Shiiki and Kawakami contain a substantially similar polyglycolic acid film. Also, the stretching conditions of Kawakami provide the correct orientation of the molecular chain, therefore providing a container that exhibits

sufficient tensile strength, and also has sufficient barrier properties, heat resistance and transparency (col. 13 lines 39-45).

It should be noted that the crystal melting point, sub-dispersion peak temperature, main dispersion peak temperature, and the orientation degree are result effective variables. As orientation of the molecular chain increases, the degree of crystallinity of the polymer becomes sufficient to prevent the formation of harmful coarse spherulites that may result in insufficient properties of the polymer film. It would have been obvious to one of ordinary skill in the art at the time the invention was made to produce a container with optimal values for the crystal melting point, sub-dispersion peak temperature, main dispersion peak temperature, and the orientation degree since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch,* 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

(10) Response to Argument

In determining the patentability of a stretched product one of ordinary skill in the art must understand the general properties of the polymer in which is used for the product. The claimed polymer is a crystalline aliphatic polyester that is glycolic acid homopolymer. Polymers can be molded in two phases, crystalline and amorphous. The polymer claimed is a crystalline polymer, meaning that the molecules are arranged closely and in a discemible order. This allows the polymers to be rigid, have a high melting point and are less affected by solvent penetration. The aliphatic part of the polymer, in broad terms, is biodegradable. In the industry, aliphatic polyesters tend to

lack thermal and mechanical properties. Thus, crystalline aliphatic polyesters are generally used for biodegradable products because they produce articles with enhanced physical and mechanical properties. To further enhance the mechanical properties of the polyester bi-axial stretching is generally preformed. Stretching allows for the polymer chains to align causing the chains to further crystallize. Thus, the crystallinity of the polymer increase which stabilizes the bulk material with respect to such properties as shrinkage and heat distortion. It is known to one of ordinary skill in the art that stretching a product will increase the physical properties of an un-stretched product, such as the crystal melting point.

Thus, the issue of debate is if an increase of a crystal melting point by at least $3^{o}C$ than that of an unstretched product by stretching the glycolic acid homopolymer at a stretching ratio exceeding 3x3 is an unexpected result.

The appellant provided a declaration on 09/26/2008. At this time during prosecution the claims claimed the broad limitation of a crystalline aliphatic polyester. The declaration provides data showing that stretching a polylactic acid homopolymer or a polyglycolic acid homopolymer at a ratio below the ratio exceeding 3x3 does not produce a film with an increased melting point of at $3^{o}C$. However, the declaration was directed towards a specific film from a previous prior art reference. The newly submitted office action combined two new prior art references.

The appellant argues that the Examiner has failed to provide any reason as to why one skilled in this art would expect intense stretching to cause a remarkable increase in the crystalline melting point of polyglcolic acid (appeal brief, pg. 10 ¶3).

In response, the primary reference used in the final rejection is Shiiki. Shiiki discloses a gas barrier multilayer hollow container that is formed from a polyglycolic acid homopolymer (abstract). Shiiki discloses that stretch blow molding is used, in which biaxial stretching is conducted upon blow molding [0052]. Shiiki discloses that stretch blow molding is a process in which stretching is conducted upon blow molding, thereby orienting the molecular chain of a polymer to enhance the physical properties of the polymer [0052]. It has been held that where general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. One of ordinary skill in the art would have been motivated to optimize the stretching conditions to enhance the orientation the molecular chain in order to enhance the physical properties of the polymer. Thus, the examiner has provided a reason as to why one skilled in this would expect stretching to cause an increase in the crystalline melting point of polyglycolic acid.

A secondary reference, Kawakami, was used to further strengthen the argument that the temperature ranges and stretching ratios are known in the art to enhance the physical properties of polyglycolic acid.

The appellant argues that Kawakami teaches broad ranges for the temperature in which the polygylcolic acid is stretched and broad stretching ratios (appeal brief, pg. 11 ¶3).

In response, Kawakami discloses a stretch blow molded container formed from a thermoplastic resin material which comprises a polyglycolic acid (abstract). Kawakami discloses that temperature conditions for preforming stretch blow molding are 70^{0}C or

lower (col. 12 lines 64-65). If the resin temperature upon the stretch blow molding exceeds 70°C, the motion of the molecular chain in the polymer becomes too hard, and there is a possibility that a state of orientation by stretching may be immediately relaxed when stretch blow molding is conducted, and so the orientation may be extinguished or reduced to a great extent (cols.12-13 lines 65-4). Kawakami discloses that if the blow-up ratio or draw ratio is lower than 1.5 the orientation of the molecular chain becomes insufficient, so that there is a possibility that the degree of crystallinity of the polymer may be insufficient, and the formation of harmful coarse spherulites may hence be brought, resulting in a stretch blow molded container which cannot exhibit sufficient tensile strength and also has insufficient barrier properties, heat resistance and transparency (col. 13 lines 37-45). Thus, Kawakami provides the general conditions of stretching a polyglycolic acid homopolymer to increase the physical properties of the homopolymer.

The appellant provides data from the specification that compares stretching ratios and the temperatures that were used for stretching the films. The examiner does not believe that the comparative examples shown in tables 1 and 2 provide enough data for one to determine that the stretching ratios and temperatures provide the unexpected result that the crystal melting point would increase by at least 3°C than that of the unstretched product when the polyester is stretched at 45-60°C at a stretching ratio exceeding 3x3 times. The data provides 3 stretching ranges, 4.5x4.5, 4.0x4.0 and 3.0x3.0. The claim states that the stretching ratio exceeds 3x3 times. This range encompasses a stretching ratio of anywhere between 3.1x3.1 to 100x100 times. The

appellant has failed to encompass the smallest end of the range and the highest end of the range in terms of the stretching ratio. The examiner would like to note that comparative examples 4-5 in tables 1 and 2 directly correlate to the disclosure of Kawakami. Kawakami stated that if the blow molding temperatures exceed 70°C, the motion of the molecular chain in the polymer becomes too hard, and there is a possibility that a state of orientation by stretching may be immediately relaxed when stretch blow molding is conducted, and so the orientation may be extinguished or reduced to a great extent (cols.12-13 lines 65-4). Thus, the enhance properties that are formed by stretching no longer exist, such as a enhanced melting point. This is clearly seen in comparative examples 4-5 of the appellant's specification.

It is the examiner's position that the appellant has failed to provide enough evidentiary support to determine if the stretching conditions that are claimed produce the unexpected result, a increase in crystal melting point of at least 3°C than that of the unstretched product, based on the teachings of the prior art and inherent properties of polymer chemistry.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/ELLEN S WOOD/

Examiner, Art Unit 1782

Conferees:

/Rena L. Dye/
Supervisory Patent Examiner, Art Unit 1782

/David R. Sample/
Supervisory Patent Examiner, Art Unit 1783